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REMARKS

The above-listed claim amendments along with the following remarks are responsive to the final Office Action dated November 16, 2004. Claims 1 and 12 are amended. Claims 2-4, 15 and 17 are cancelled. After entry of this Amendment, claims 1, 5, 6, 12-14 and 16 are pending. Applicants respectfully request reconsideration of this application.

Claim Amendments

Claims 1 and 12 have been amended to recite a syringe containing a bulking agent, a hypodermic needle connected to and extending between about 1.5 and about 5 inches from the syringe, the needle having a linear segment extending from a hub of the syringe and an arcuate segment formed by about a 15 degree bend located within a position of the needle closest to a needle tip. This system injects a bulking agent into a tissue plane between a rectum or urethra and its surrounding sphincter muscle. Amended claims 1 and 12 are fully supported by the application and claims as originally filed. No new matter is introduced into the application by the claim amendments.

Claim Rejections – 35 U.S.C. § 102

Claims 1-5, 12, 15 and 17 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,666,848 to Stone, in particular by Figure 3. The Office Action stated that Stone reports an apparatus comprising a syringe containing a bulking agent and a needle with a bend.

Applicants respectfully submit that Stone is not a proper 35 U.S.C. 102(e) reference because Applicants conceived and reduced the present invention to practice before June 14, 2001, the effective date of the Stone reference.

Applicants submit the Declaration of co-inventor, Dean A. Klein (the "Declaration"). As stated in the Declaration, Mr. Klein is employed by Carbon Medical Technologies in the position of President and Chief Executive Officer. The Declaration further states that Mr. Klein, along with Raymond Rackley and Kristina Wittchow jointly conceived and reduced to practice the present invention before June 14, 2001. Accompanying this response in support

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of the Declaration is a copy of the Invention Disclosure with dates redacted. Applicants respectfully request withdrawal of this rejection.

Claims 1, 5-6, 12 and 15-17 were rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,258,067 to Hill. Claims 1, 2, 5, 6, 12 and 15-17 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 1,569,174 to Crowther and claims 1, 3-6, 12 and 15-17 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 4,518,383 to Evans.

Applicants respectfully submit that neither Hill, Crowther, nor Evans anticipates the claims as amended. For a reference to anticipate a claimed invention, the reference must specifically teach every element of the relevant claim(s).

Hill does not anticipate claims 1, 5-6, 12 and 15-17 because Hill does not report an apparatus for injecting a bulking agent. Rather, Hill reports an apparatus designed to withdraw bodily fluids. Crowther does not anticipate claims 1, 2, 5, 6, 12 and 15-17 because Crowther does not report a needle that can inject a bulking agent. Furthermore, Crowther is silent with respect to the needle lengths and bend angles. Finally, Evans does not anticipate claims 1, 3-6, 12 and 15-17 because Evans does not include a syringe housing a bulking agent.

Applicants respectfully submit that neither Hill, Crowther nor Evans anticipate, or teach or suggest the claimed invention because none of the references report a system that includes the combination of features recited in the amended claims 1 and 12, specifically a syringe containing a bulking agent and a needle extending between about 1.5 and about 5 inches from the syringe with a 15 degree bend.

Indeed, the deficiencies noted above in Hill, Crowther and Evans are evident by the Examiner's introduction of the Stone reference, which does report a bulking agent. Because neither Hill, Crowther and Evans report a bulking agent, these references do not anticipate the claims as amended. As noted previously, Stone is an improper 102 (e) reference.

Claims 1, 5-7 and 12-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,792,478 to Lawin et al. in view of Hill. The Office Action stated that Lawin et al. reports the injection of a bulking agent but does not disclose a bent needle. The

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Office Action stated that Hill, however, reports a syringe having a bent needle. According to the Office Action, it would be obvious to modify the delivery device reported in Lawin et al. with a bent needle and shield reported by Hill.

Applicants assert that Lawin et al. in view of Hill does not teach or suggest the system recited in amended claims 1 and 12 because the apparatus reported in Hill is configured to withdraw bodily fluids rather than to inject a bulking agent such as the bulking agent reported in Lawin. Lawin does not report the use of a bent needle to inject bulking agents. Thus, a person of ordinary skill in the art would not be motivated to combine Lawin and Hill because the apparatus reported in Hill is designed to withdraw bodily fluids rather than inject a bulking agent.

For the reasons set forth above, Applicants respectfully request withdrawal of the rejections as it applies to the pending claims 1, 5, 6, 12-14 and 16.

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CONCLUSION

All of the pending claims are in condition for allowance. Applicants request a notice to that effect. If there are any remaining questions, the Examiner is requested to contact the undersigned at the number listed below.

Respectfully Submitted,

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